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Context-Driven Design of a Laparoscopic Instrument Cleaner for Use in Rural Low-Resource Hospitals

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Laparoscopic surgery offers significant benefits to patients in low-resource settings compared to open surgery such as faster recovery, less pain, and lower infection rate. However, there exist significant barriers to the safe introduction of laparoscopy such as high costs and limited availability of trained staff. Low- and middle-income country (LMIC) hospitals suffer from higher post-surgical infection which might be due to the limited facilities for the sterile reprocessing of laparoscopic instruments. To design a solution to this issue, a detailed understanding of local settings was needed. Therefore, this research applied a context-driven design approach, based on the Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide. Over several design phases, the need for a reprocessing device was established. An analysis of the sterile reprocessing of laparoscopic instruments led to a list of context-specific design requirements. These were translated to a final conceptual design of a laparoscopic instrument cleaner using a waterfall design method. Finally, a usability study of the loading system of the device was conducted with nurses in four Indian hospitals. A root-cause analysis of the usability study showed that the device was not intuitive enough to use for Indian nurses. A redesign of the loading system was made to improve its ease of use. The design process used in this study can be used as an example for designers wanting to address the critical issue of context-specific medical devices worldwide, or more specifically, the sterile supply of surgical instruments in resource-constrained environments. [DOI: 10.1115/1.4066473]

Keywords: laparoscopic surgery, low-resource hospitals, instrument reprocessing, context-driven design, sterile reprocessing, usability study, Indian hospitals, medical device design, rural healthcare

Introduction

The 2015 the Lancet Commission Global Surgery Report brought to light the limited access to safe surgery faced by five billion people, particularly in low- and middle-income countries (LMICs). The report emphasizes the importance of investing in surgical services, as it is not only affordable but also saves lives and promotes economic growth [1]. So far, we have seen various initiatives emerging from this call for action, often in the form of surgical training programs in LMICs [2–4]. However, the introduction of modern surgical techniques, such as laparoscopic surgery, has been slow [5].

Laparoscopy is a widely used surgical treatment in high-income countries (HICs), in which the surgeon uses long, slender instruments inserted through tiny incisions in the skin to perform surgery in the abdominal cavity. Patients treated laparoscopically can be discharged from the hospital sooner thanks to advantages such as lower mortality, lower pain rates, and a lower infection rate compared to conventional open surgery [6–8]. These benefits might even have a greater impact in LMICs than in HICs, where workers often rely on day wages as their main form of income.

However, it is believed that this type of surgery is inaccessible to patients in LMICs [9]. A review by Chao et al. uncovered systemic barriers to laparoscopic surgery in LMICs, including a limited availability of trained staff, training opportunities, limited resources, and equipment [10]. Many LMIC hospitals do not have facilities available to adequately sterilize surgical equipment [11,12]. Fast et al. found that none of the reprocessing facilities of hospitals in three different LMICs complied with the World Health Organization-recommended standards for surgical instrument reprocessing because of untrained staff, missing supplies, incorrect storage, and broken equipment [13].

These barriers hamper the safe introduction of laparoscopy and contribute to a higher postsurgical infection in LMIC hospitals (that have managed to introduce laparoscopy) compared to HIC hospitals [7,14]. One cause for the higher infection rate in LMICs is related to the reprocessing of laparoscopic equipment [15–17]. To combat complications due to unsafe reprocessing, surgeons administer perioperative antibiotics. However, because of a global increase in antibiotics use, there is a growing concern for resistant organisms [18].

There are initiatives focusing on the development of innovative laparoscopic equipment that fits the context of use in LMICs [19,20]. Although specific devices intended to clean laparoscopic instruments exist, they are designed to operate within the conditions of a HIC central sterilization department. For LMIC hospitals, the

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requirements relating to the context, such as unavailable spare parts, absence of maintenance programs, and a harsher operating climate, must be considered [1,21,22]. Hence, to ensure that laparoscopic surgery can be safely practiced in LMIC hospitals, the issue of reliable reprocessing must be addressed.

Therefore, the goal of this paper is to present the design method of a laparoscopic instrument cleaner, specifically for LMIC hospitals. The applied context-driven design approach is based on the Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide [20], extended with structured interviews, observations, and surveys [23]. The design method resulted in a detailed description of the context of low-resource hospitals in India which were used as the basis for a set of context-specific design requirements. A nonfunctional prototype was developed to show the proof of concept. Finally, a usability evaluation with Indian nurses was performed to test the early prototype and receive valuable feedback for a following design iteration.

Methods

The roadmap for the design of safe surgical devices for low-resource settings, which was used as a template for the design process [24], consists of four phases (Phases 0–3). Over a period of 4 years, four studies were conducted to gather the data to fulfill the phases. Three studies were conducted in urban and rural hospitals which are peripheral hospitals, in areas with low population densities in India. Table 1 shows an overview of the field studies that were performed (Studies A–D).

Ethical clearance for the field visits was given by the Human Research Ethics Committee of the Delft University of Technology (Delft, The Netherlands, reference numbers: 679, 1063, and 2499) and the Institutional Ethics Committee (IEC) of Maulana Azad Medical College (New Delhi, India, reference number: F.1/IEC/MAMC/73/01/2020/No48).

Phase 0: Evaluation of the Needs Around Laparoscopy in Rural India. Phase 0 assessed the need for a surgical device. During study A, two researchers, D.R. and T.L. (see the Acknowledgment), evaluated the needs of Indian hospitals relating to laparoscopic surgery by conducting a survey in two locations in 2019. These were the general council meeting of the Association of Rural Surgeons of India in Bagalkot, Karnataka, and a training session of gasless laparoscopic surgery for rural surgeons in Kolkata, West-Bengal, India. The on-paper survey consisted of 40 multiple-choice and open questions about the type of hospitals, available equipment, barriers that surgeons face when introducing laparoscopic surgery in rural and urban hospitals, and methods they used to reprocess the laparoscopic instruments.

The survey was completed by 12 rural surgeons, of which ten had experience in laparoscopy. Besides this survey, the two researchers observed four surgeries performed by rural surgeons during two days of the training session in Kolkata. These observations were recorded by means of photographs and notes of conversations with surgeons.

Phase 1: Context of Laparoscopic Instrument Reprocessing. Phase 0 established the need for a device that improves laparoscopic instrument reprocessing in India. After this, Phase 1 of the roadmap studied the context under which the device was to be used by determining the barriers to safe surgery and recording specific aspects of safe surgery. In this project, it concerned the context in relation to the reprocessing of laparoscopic instruments in India, which was studied in studies B and C.

Study B identified the barriers related to current reprocessing methods in four rural hospitals in three different states in India: Jharkhand, Tamil Nadu, and Assam. Data were collected by D.R. using semistructured interviews with two surgeons and two nurses, and checklist observations to identify the reprocessing methods. The items of the checklist were based on (inter)national guidelines, expert recommendations, and previous experiences [26–30]. One outcome of Study B, published by Robertson et al. in 2021 [25], was a detailed description of the reprocessing methods used in the rural hospitals. Moreover, relevant barriers were related to issues local healthcare workers encounter in the sterile supply of surgical instruments and to methods used in reprocessing laparoscopic instruments.

In Study C, observations were performed of the methods used in the reprocessing cycle of laparoscopic instruments in two hospitals in the Netherlands. Data were collected by D.R. and A.K. by taking photographs and making notes. The data were used to make a comparison with the reprocessing methods recorded in India in Study B.

Phase 2: Design Requirements for a Laparoscopic Instrument Cleaner. Findings from Phases 0 and 1 were projected into a product journey of laparoscopic instruments to provide a visual representation of the reprocessing cycles of Indian and Dutch hospitals. This visual representation was used to determine the critical stages in which the device was intended to operate.

To find the design requirements in Study C, A.K. and D.R. conducted semistructured interviews with experts in the field of reprocessing surgical instruments. The design team spoke with an expert in reprocessing in a Dutch hospital, an expert in reprocessing in LMIC hospitals, and an Indian rural surgeon in a period between 2021 and 2022. Requirements that were mentioned during the interviews in Phases 0 and 1 were also included. The results of the studies in this Phase 2 led to a set of context-specific design requirements. Besides these, a review of scientific literature on the cleaning of surgical devices [26–30] and ISO standards including ISO 15883-5 formed a set of technical design requirements [31].

Phase 3: Act

Translating Insight Into Design Solutions. During Phase 3, the synthesis stage of the design process of a laparoscopic instrument cleaner was started based on a waterfall design method [23]. First, a function analysis of the laparoscopic instrument cleaner was

Table 1 Overview of the field studies that were performed

Study No.	Date	Phase No.	Study type	Number of participants	Visited hospitals	Location
A	2019	0	Survey, observations of laparoscopic surgeries in India	Ten laparoscopic surgeons[a], Two general surgeons[a]	One urban tertiary, One rural district	Karnataka, West-Bengal, India
B[b]	2020	1, 2	Survey, semistructured interviews, and observations in rural Indian hospitals	Two nurses [NB1–2], Two laparoscopic surgeons [LB1–2]	Four rural district	Jharkhand, Tamil Nadu, Assam, India
C	2023	2	Semistructured interviews with experts	One LMIC reprocessing expert [ELC1], One HIC reprocessing expert [ELC1], One laparoscopic surgeon [LC1][a]	—	The Netherlands
D	2023	2, 3	User evaluation and semistructured interviews with Indian nurses	Five urban nurses [NUD1–5], Four rural nurses [NRD1–4], Three nursing students [SD1–3]	Three rural district, One urban tertiary	Assam, Tripura, Delhi, India

[a]A laparoscopic surgeon is trained to perform laparoscopy, as opposed to a general surgeon who is not trained in laparoscopy.
[b]Study B was published by Robertson at al. in 2021 [25].

performed to meet the full set of design requirements. Then, three concepts were created using morphological charts, which were turned into three physical mockups that were evaluated by the experts of Study C. Their feedback was incorporated into a final concept, consisting of several subsystems such as the mechanical cleaning system and the loading system of the laparoscopic instruments. The loading system should save time and be intuitive to use with limited additional training of staff. Therefore, evaluating the design of the loading system was the focus of the evaluation during Phase 3. To do this, a nonfunctional prototype was made based on the final concept of the loading system. The prototype consisted of two parts: a nonfunctional housing that contained a simulated washing chamber with a nonfunctioning control panel, and two loading baskets designed to contain the laparoscopic instruments (shown in the Results section). After the evaluation, another iteration of the design was made.

Usability Evaluation Study. To evaluate the loading system, Study D evaluated whether it was intuitive for nurses in India to load laparoscopic instruments into the loading baskets of the prototype, without any prior explanation. The study was conducted in one urban and three rural hospitals in the states Delhi, Tripura, and Assam. The participant groups included in the study are shown in Table 1 and Fig. 1. All of the participants had experience in handling laparoscopic instruments (urban nurses: 11–27 yr, rural nurses: 3–25 yr, and nursing students: 2 yr), but none had previous experience using automatic cleaners or washer disinfectors.

Protocol. The evaluation started with a short verbal introduction of the aim of the study and a general explanation of the prototype. After this, informed consent from the participant was obtained. The participant was then given a leaflet explaining the laparoscopic instrument cleaner and its functions. The hands-on tasks during the tests were recorded with a camera, and the audio of the interviews was recorded. An overview of the protocol is provided in Fig. 1.

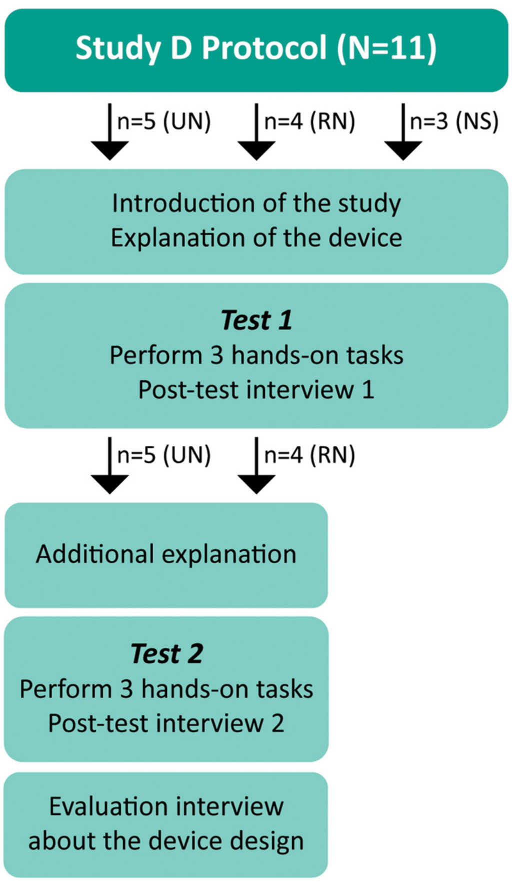

Fig. 1 Protocol of the usability evaluation study

A task analysis, performed prior to the study, identified three main tasks as most critical to load laparoscopic instruments into the instruments. These were unloading the baskets from the cleaner, loading the instruments into the baskets, and loading the baskets back into the cleaner. The main part of the study consisted of two parts: Test 1 and Test 2 (see Fig. 1), where the participants were asked to perform the three tasks. During Test 1, the participants were asked to load one set of laparoscopic instruments (which was the same for all participants) into the baskets without any explanation about where to place them. Before Test 2, the participants were informed which instruments belonged to which baskets, but no additional information was provided where and how to place them in the basket. Then, the participants performed the three main tasks again. Each test was followed by an interview to debrief about behind the participant's actions. Finally, participants were asked questions about what their overall perception was of the device. The nursing students only participated in Test 1 because the large amount of time needed for them to complete the first test.

Data Collection and Analysis. All interviews, study notes, and photographs were transcribed and coded using ATLAS.TI (23.1.1.0, ATLAS.ti Scientific Software Development GmbH, Berlin, Germany) by D.R. and A.K. The barriers to safe reprocessing were determined by coding the interviews conducted in all phases. The codes were grouped into cultural barriers, financial barriers, and structural barriers, according to the design for safe surgery roadmap [24]. The interviews conducted in Phase 3 were analyzed to determine recommendations and further design requirements.

Study A involved a questionnaire with 40 questions to assess the general needs concerning laparoscopy in India. Only the questions concerning the reprocessing of laparoscopic instruments were included in this paper. The data of Study D were analyzed to determine which type of use error occurred. The participant comments from the interviews and observations from the camera recordings were used to perform a root-cause analysis. The type of use error was categorized according to IEC 62366-1:2015/Annex D (International Electrotechnical Commission, 2015) and were divided into three categories: perception errors, cognition errors, and action errors [32,33].

Results

During the four-year period, with three field studies in India (Table 1), 18 semistructured interviews were conducted with 17 healthcare workers.

Phase 0: Needs Assessment in Reprocessing Laparoscopic Instruments. The survey (Study A, surgeons 1–12) in which the surgeons were asked to indicate the methods that their hospital used in the reprocessing of laparoscopic instruments revealed mixed results. All surgeons indicated that an autoclave was available in their hospital; however, only 8 out of 12 indicated that the laparoscopic instruments were always sterilized in between procedures. Only 5 out of 12 surgeons indicated that the instruments were also disassembled, and 4 out of 12 indicated that they were visually inspected.

Because of their complexity, laparoscopic instruments need a rigorous reprocessing procedure to sufficiently sterilize them. The observations performed during the surgical training session in West-Bengal (Study A) and survey confirmed that manual cleaning and chemical disinfection was the default method to reprocess laparoscopic and general surgical instruments (see Fig. 2). Soaking instruments in high-level disinfectant was considered a form of sterilization which replaced conventional steam sterilization, which was confirmed after consulting one nurse and one surgeon. This explained the high response to the question whether the laparoscopic instruments were always sterilized between procedures. The current methods posed a challenge for nurses that reprocess the instruments

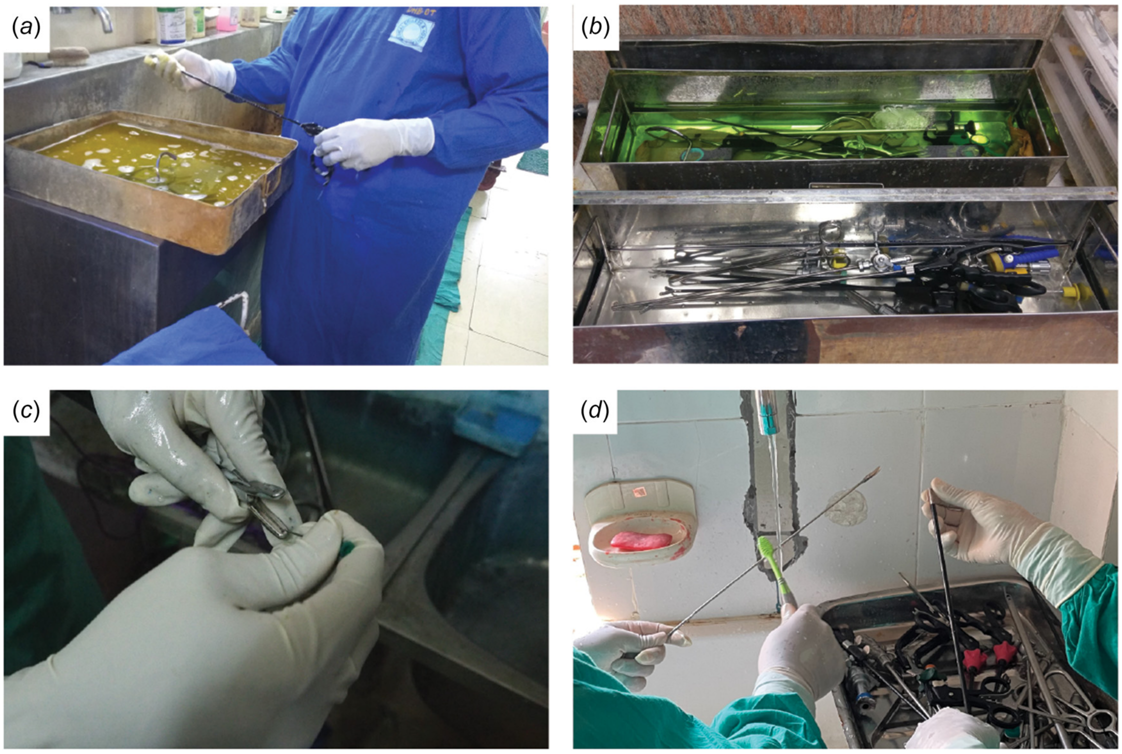

Fig. 2 Observation examples of cleaning. (*a*), (*c*), and (*d*) Nurses manually cleaning the laparoscopic instruments after surgery. (*b*) Laparoscopic instruments being disinfected in CIDEX and rinsed in saline solution.

and were a hazard to patient and staff safety. Therefore, the issues uncovered during Study A showed the need for a solution to aid nurses to reprocess laparoscopic instruments.

Table S1 available in the Supplemental Materials on the ASME Digital Collection shows the type of hospitals the rural surgeons of Study A worked in. The nine surgeons that operated laparoscopically worked in secondary (six out of nine), community (1), private (1), and tertiary hospitals (1). Primary, secondary, and tertiary hospitals in India are public hospitals, as opposed to private hospitals. Community hospitals are similar to secondary hospitals but do not receive government funding.

Phase 1: Context of Reprocessing Surgical Instruments

Phase 1.1: Barriers to Safe Reprocessing of Laparoscopic Instruments. We collected information on perceived barriers for laparoscopic surgery in rural Indian hospitals in the interviews conducted in all phases ($n=17$; laparoscopic surgeons: $n=3$, experts: $n=3$, and nurses: $n=11$). Table S2 available in the Supplemental Materials lists the identified barriers, which are further elaborated below.

Cultural barriers. With regards to surgical instrument reprocessing, the cultural barriers exist mainly in the form of the roles of the nurses and the surgeons, and the education that the nurses receive.

Education of rural nurses—The education of nurses is a barrier in reprocessing laparoscopic instruments. Cleaning and sterilization of surgical instruments is part of their general nursing education, but none of these nurses were taught how to handle laparoscopic instruments. Newly employed nurses in the hospital are taught the reprocessing methods by the more senior nurses in the hospital: *[I have not received] "special training for laparoscopic instruments. […] So laparoscopic surgery, I have not seen many times. But open I have."* [ND6]

Role of the surgeon—Another barrier is that nurses are dependent on the surgeon for guidance, although the surgeons do not have detailed knowledge or official responsibility over the reprocessing of surgical instruments: *[Responsibility of reprocessing surgical instruments is] "not the surgeons task at all. He could question it, but he cannot comment on it because it is taken care of by the nurses. You know, the sensible thing, if I have a problem I could always question and maybe audit it and to see if there is something going wrong with the process. A surgeon can do that. But the accountability of the process lies with the nurses."* [LB1]

Role of the nurse—In rural hospitals, there was one team of nurses that execute all the tasks surrounding surgery. Besides reprocessing the surgical instruments, the nurses had many tasks, such as pre- and postoperative care of the patient, assisting in surgery, and cleaning the operating room: *"So it is a multirole model system that at the moment in rural India we follow. So it is not just a scrub nurse or not as a circulating nurse, it is all the roles will be melted together. So there are no specific cleaning staff, particularly in rural setups."* [NB2]

Financial barriers. Two financial barriers were identified during the interviews: The cost of equipment which refers to either new surgical instrument, or equipment that staff could use in reprocessing, and the cost of staffing and training.

Cost of equipment—Both nurses and surgeons indicate that there is a financial barrier against buying better reprocessing equipment: *"And bio-enzymes at the moment we are not using in the rural setup till now. It is because it is not affordable by them."* [NB2]

Cost of staffing and training—Training and staffing are not a financial priority to hospitals: *"People do not want to spend money on maintenance. The hospital management often considers it unnecessary to reserve a budget for training of nurses and engineers."* [ELC1]

Structural barriers. Five structural barriers were identified.

Access to information—Although the responsibility of the reprocessing cycle lies with the nurses, they have difficulty in finding new information to research new techniques or when they encountered instruments they have not worked with before. Additionally, India has many languages, and not everyone is proficient in the official languages. This makes information even harder to find in some regions: *Researcher: "If you have new instruments that you do not know how to clean. Do you know where to find extra information to clean it?" Nurse: "No." Researcher: "So who do you ask if you do not know how to clean something?" Nurse: "The surgeon."*

Researcher: "Do you have instructions for cleaning the instrument. Like on paper?" Nurse: "No, nothing." [NB1]

Time—There is time pressure on the operating room nurses and helpers, while reprocessing the laparoscopic instruments. The nurses described they need between 15 and 30 min to clean the laparoscopic instruments and about 1 h to fully reprocess them. Because of all the other tasks, they indicated that they do not have enough time to properly reprocess the laparoscopic instruments: *"We have lots of work. We have to see other patients. We need to arrange the patient, we need clean everything. And sometimes we also have no time to rest."* [NRD4]

Availability of surgical instruments—Many of the hospitals have one set of laparoscopic instruments: *"Speed, that is important because we need to wait between the cases so that, since we only have one scope, that actually would be useful if it could to some degree be shortened."* [LB2]

Availability of equipment—Hospitals do not have reprocessing equipment specific to laparoscopic instruments. *"Second, again, as I mentioned, maybe it is to do with a little bit of financial crunch, also. That they have [not] been able to afford the correct instrument and the correct methods."* [LB1]

Availability of staff—Staff shortages were mentioned as a barrier, and hospitals often have one team of nurses: *"We do not have that much staff. The staff shortage is also there sometimes."* [NB2]

Phase 1.2: Aspects of Reprocessing

Reprocessing journey. Based on the observations in four rural hospitals (Study B), we constructed an instrument journey, showing the differences in reprocessing of laparoscopic instruments between HIC hospitals and rural LMIC hospitals (Fig. 3).

Aspect: High-income country central sterilization department. In HIC hospitals, surgical instruments are transported to the central sterilization department (CSD) where they are reprocessed by dedicated staff that are trained in sterile reprocessing. Instrument reprocessing at a CSD is a continuous process which gives staff enough time to execute all reprocessing steps resulting in a consistent outcome. Multiple instrument sets are needed when working with a central setup, allowing for sets to be reprocessed while others are used in surgery.

When instruments are brushed and rinsed, droplets of water containing micro-organisms are aerosolized, which can contaminate surrounding surfaces and infect people. A CSD is designed to have a floorplan which separates the processing of dirty, clean, and sterilized instruments. The floor plan prevents cross-contamination between instruments that have just been used and those that have already been sterilized. Furthermore, staff handling the dirty instruments wear personal protecting equipment like masks, water-proof gowns, and gloves.

Aspect: High-income country reprocessing methods. Because of the geometry of laparoscopic instruments, several cleaning steps are performed to ensure all bioburden is removed. Debris is first removed in precleaning in sinks with water guns and ultrasonic cleaners. After this, they are automatically cleaned in washer disinfectors, which also dry the instruments. Then, the cleanliness of the instruments is manually inspected before the instruments are wrapped and sterilized.

Aspect: Indian infrastructure. None of the four hospitals reprocessed the laparoscopic instruments in the CSD. Most of these hospitals lack a CSD. Only one has a CSD, but it was not actively used. Instead, the laparoscopic instruments are collected after surgery and transported to a sink, either in the operating room or in an adjacent room in the operating room environment. These areas lack the facilities of a CSD such as treated water or personal protecting equipment and do not have a layout to prevent cross contamination.

Aspect: Indian equipment. The Indian hospitals in this study own only one set of laparoscopic instruments, and this set has to be reprocessed between each surgery. Specific reprocessing equipment is unavailable: toothbrushes are used to clean the instruments' surfaces, and hypodermic needles and scalpels to remove debris from difficult to reach areas of the laparoscopic mechanisms (Fig. 2). Only one hospital has an automated cleaner available which is not in use. Three of the four hospitals are equipped with manual steam sterilizers of different types. However, the laparoscopic instruments are not steam sterilized because of concerns that the heat damages the components.

Aspect: Indian reprocessing methods. All steps of the reprocessing cycle are performed manually by the nurses. After cleaning, the

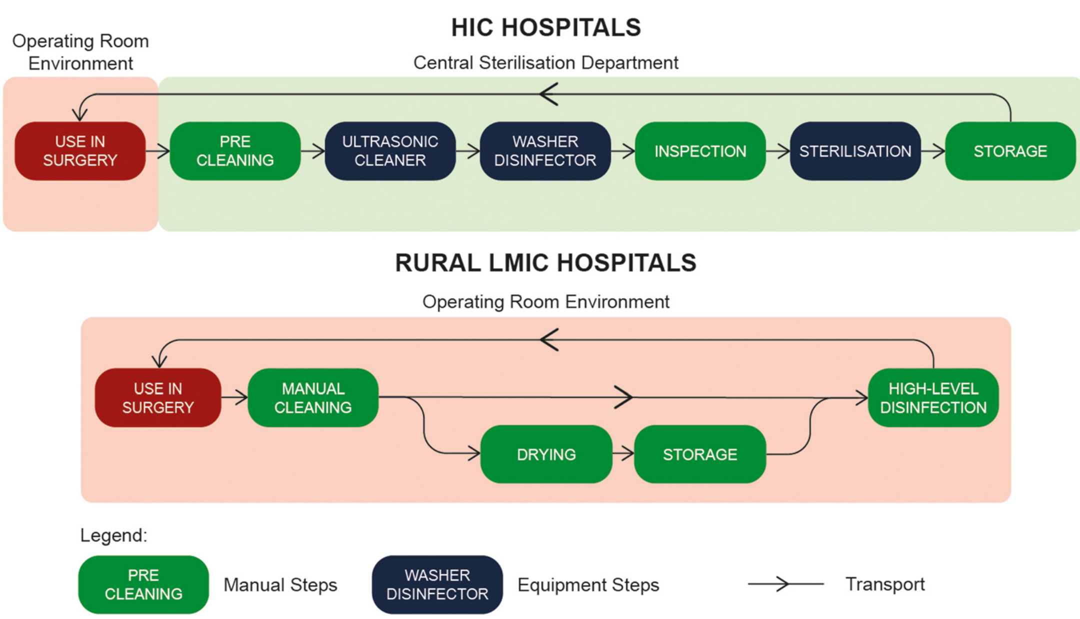

Fig. 3 Instrument journey describing schematic the reprocessing cycles in LMICs and HICs

Table 2 Key challenges to reprocessing laparoscopic instruments in Indian hospitals

Infrastructure	Lack of a CSD	Construction of a CSD is financially unfeasible. Cleaning instruments near operating room is a contamination hazard.
	Reprocessing equipment	Reprocessing equipment such as detergent and suitable brushes are unavailable
Instruments	Complex cleaning of laparoscopic instruments	Cleaning of laparoscopic instruments involves multiple time-consuming steps. Quality of cleaning affects disinfection or sterilization.
	One laparoscopic instrument set	The laparoscopic instrument set must be reprocessed in between surgery which limits time that can be spent on reprocessing.
Staff	Education and training	Nursing education does not incorporate laparoscopy, and finding new information is difficult.
	Staff safety	The needles and scalpels used for cleaning can injure nurses and transfer contaminants.

instruments are rinsed under tap water and deposited into a container with the high level disinfectant glutaraldehyde or formalin gas. In one hospital, the instruments are dried before being disinfected; in other hospitals, the instruments are only air-dried at the end of the day to store them.

Glutaraldehyde fixates unremoved bioburden on the instruments' surface, making them even more difficult to clean over time. This means that disinfection cannot be guaranteed when the cleaning methods are unreliable.

Phase 2: Design Direction and Design Requirements

Key Challenges. The analysis of the context shows that there are many factors that contribute to insufficiently processed laparoscopic instruments. Table 2 shows a summary of the key challenges that are identified during Phases 0 and 1, which are divided into three groups: staff, infrastructure, and instruments.

Design Direction. Based on the key challenges, the design direction was to develop an automated laparoscopic instrument cleaner which is designed to operate in the context of an operating room environment of an LMIC hospital. The proposed solution resulted in a new reprocessing journey (see Fig. 4). Because the cleaner is kept in the same environment, the journey does not greatly differ from the current journey (Fig. 3). However, the proposed journey includes an inspection step, which is crucial to the reliability of the process, and steam sterilization, which is the preferred method for laparoscopic instruments.

Design Requirements. As a result of studies A–C and the review of ISO 15883-1, design requirements were established and are presented in Table S3 available in the Supplemental Materials on the ASME Digital Collection.

Phase 3: Act

Translating Insight Into Design Solutions. The laparoscopic instrument cleaner was developed during Phase 3. Three iterations of the waterfall design method resulted in a final concept design (Fig. 5). The laparoscopic instrument cleaner, intended to operate in the operating room environment (requirement G1), can be filled either by connection to a water main or manually. The device cleans only laparoscopic instruments; this way, the wash chamber can be kept compact to limit its footprint (requirement G2). Washer-disinfector machines in CSDs have a disinfection cycle after washing the instruments which makes the instruments safe to handle by healthcare workers. Because in LMIC hospitals the instruments are directly disinfected after cleaning, it was chosen not include a thermal disinfection phase which also shortens the cycle time (requirement G7).

The cleaner was designed to clean one set of instruments per cycle as per requirement O4. The disassembled instruments are loaded into two baskets by the nurses. The design of the baskets is based on what is currently used in industry. Basket 1 carries the handles, inserts, and other small parts, and basket 2 carries the hollow components. This allows for flushing of the hollow components and exposes enough surface area for cleaning. Baskets are loaded vertically to allow for the hollow components to drain fluids. Surface cleaning is done by spray jets inside the wash chamber, and the lumens are cleaned by forcing water forced through the lumen by an alternating flow mechanism (requirement C2). The cleaning program includes a precleaning with water of surfaces and lumens, cleaning with water and detergent of surfaces and lumens, ultrasonic cleaning of mechanism tips, and rinse with water (requirement G4–7, C1).

Usability Evaluation Study. Figure 6 shows the prototype that was made based on the final concept and used for the usability evaluation in Study C. Table 3 shows the tasks the nurses performed, the use errors (according to IEC62366-1:2020 Annex D), the root causes for the errors, and the time the nurses spent per test. The results show that no participant was able to perform all tasks correctly. During the first and second tests, the nurses made 4.4 and 2.4 use errors on average, respectively. On average, urban and rural nurses made a similar number of errors in the first test (4.6 and 5.4), respectively. Only one of the tasks (A6) was performed without any errors. The urban nurses on average took 7:11 min (ranged between 02:49 and 09:45 min), the rural nurses 06:46 min (ranged between

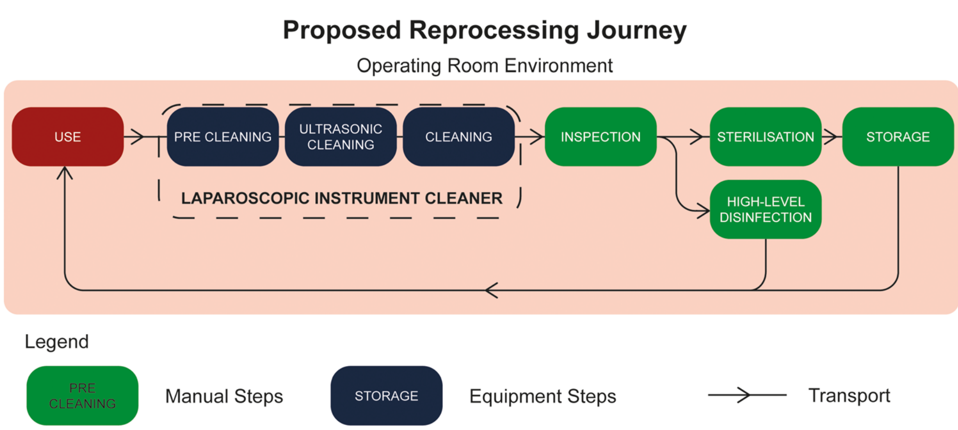

Fig. 4 New reprocessing journey with the steps that the new device is intended to automate

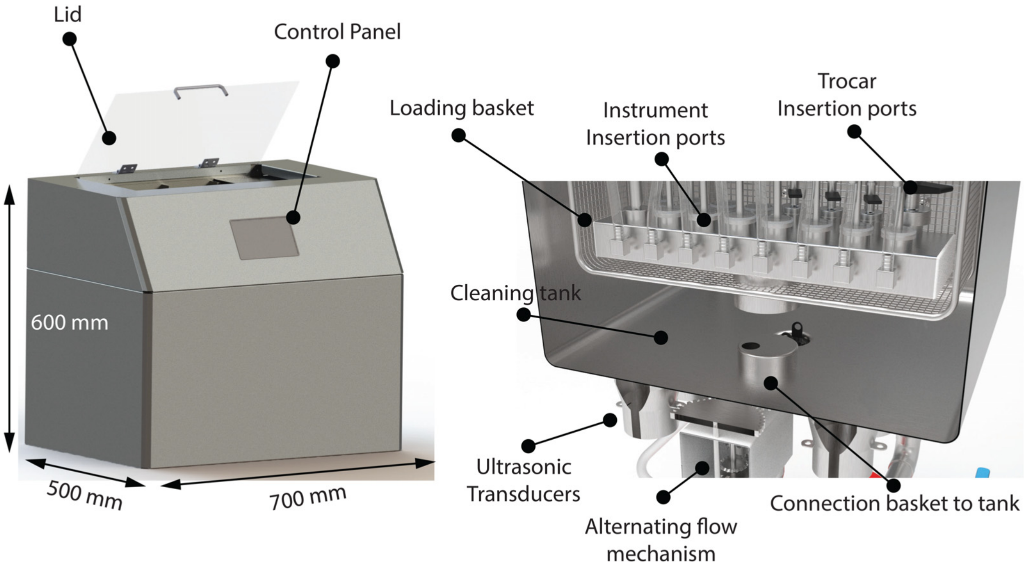

Fig. 5 Renders of the casing of the laparoscopic instrument cleaner (left) and a detail of the connection between the basket and the wash chamber (right)

02:55 and 14:30 min), and the nursing students 15:58 min (ranged between 12:20 and 21:05 min).

Use errors. Tasks A2–A5 and B1–B3 were placing items in the correct location in the baskets. None of these seven tasks were performed without errors in either test. In the debrief interviews, the nurses mentioned that the baskets did not convey enough information where to place an item causing cognition errors. The nurses placed items in other locations, for instance, placing the obturators loose in the basket and commented: *"I am not sure where I should put it"* [NUD1]. Another reason for placing items in another locations than intended was to prevent damage to the parts. The nurses tried to prevent this by either ensuring that parts would not fall down in the vertical baskets, or that the plastic parts would not contact sharp metal edges: *"I put the inserts and the black sheaths in a different box from the trocars. As the inserts and black sheaths get damaged more easily"* [NUD2]. *"It is fixed which means it will not be broken"* [NRD2].

When nurses were unsure where to put a certain item they looked for a location based on geometry: *"I think it is okay. The length is appropriate for this one"* [NUD1].

The nurses also tried to prevent damage to the baskets themselves. In one of the ports, the nurse was unable to fit the black tubes into the hole of the port, leading to an action error: *"I put the black sheaths there because rubber stand it. It is designed for black sheath. The flush port has a very small hole to install it"* [NUD5].

Correct uses. The nurses who correctly executed a task did this for different reasons. The nurses correctly placed items if they could securely fasten it. *"It is designed in such a way. It clamps it"* [NRD1]. For other parts, the correct location provided information where to place it, for instance, with the handles: *"For the handles the hooks are meant there"* [NUD1].

With only one task (B2: Load lumens of trocars on the rods on the manifold), two of the nurses gave a rationale related to the cleaning of the part: *"The trocar is more contaminated, so in this location it has more space to be cleaned* [NUD2]*": "The aluminum fixes the instrument and trocars are hollow, the inside will be [cleaned]"* [NRD4].

Evaluation Interviews. Nine nurses participated in the evaluation interviews [NUD1–5, NRD1–4] and provided general feedback on the device design and its (potential) value within the reprocessing cycle. The nurses mentioned that the cleaner could save time during the reprocessing cycle and decrease the work pressure currently put on them (9x), loading the baskets is comfortable (5x), although the baskets are a little heavy and need to get habituated to the mechanism (1x), the cleaner is a more reliable system for cleaning the laparoscopic instruments compared to the current system of manual cleaning (5x), expect less damage to laparoscopic instruments when using the instrument cleaner (3x), working with the cleaner would increase the work safety during the cleaning process by decreasing the amount of physical contact with the contaminated instruments (3x), and expect the laparoscopic instrument cleaner to use less water than when the instruments are manually cleaned under continually running tap water (2x).

Prototype Iteration 2: Redesign Based on Usability Study. Based on the results of the user evaluation, we developed a redesign of the laparoscopic instrument cleaner (Fig. 7). Most of the errors made during the instrument loading tasks had root causes relating to cognition. Therefore, instruction diagrams were added to the surface of the washer (see Fig. 7(*c*)) to support nurses with varying levels of experience in loading washer disinfectors in properly positioning the instruments into the trays.

Discussion

This paper outlines the approach taken to develop a device aimed at enhancing the sterility of laparoscopic instruments in LMIC hospitals, by focusing on the design of the laparoscopic instrument cleaner. Based on the Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide, Phase 0 uncovered the need for such a device. Then, studies of the context in Indian hospitals produced a set of context-specific design requirements which led to a concept. Finally, the loading system of the concept was evaluated in the usability study of its loading system with local nurses which updated the concept into the final design of the laparoscopic instrument cleaner.

An automated cleaner has the main benefit of providing a reliable level of cleaning without being dependent on the time that the nurses have to spend on reprocessing or what their training level is. Lower levels of bioburden improve the outcome of the sterilization or disinfection steps. Contamination due to aerosolization is reduced because cleaning is contained within the device. Additionally, nurses' safety and longevity of the laparoscopic instruments is expected to improve because manual cleaning is no longer performed with toothbrushes, needles, and scalpels.

Especially for complex equipment such as laparoscopic instruments, automatic cleaning has been proven to be more effective than manual cleaning [34]. This is because it ensures that all surfaces of

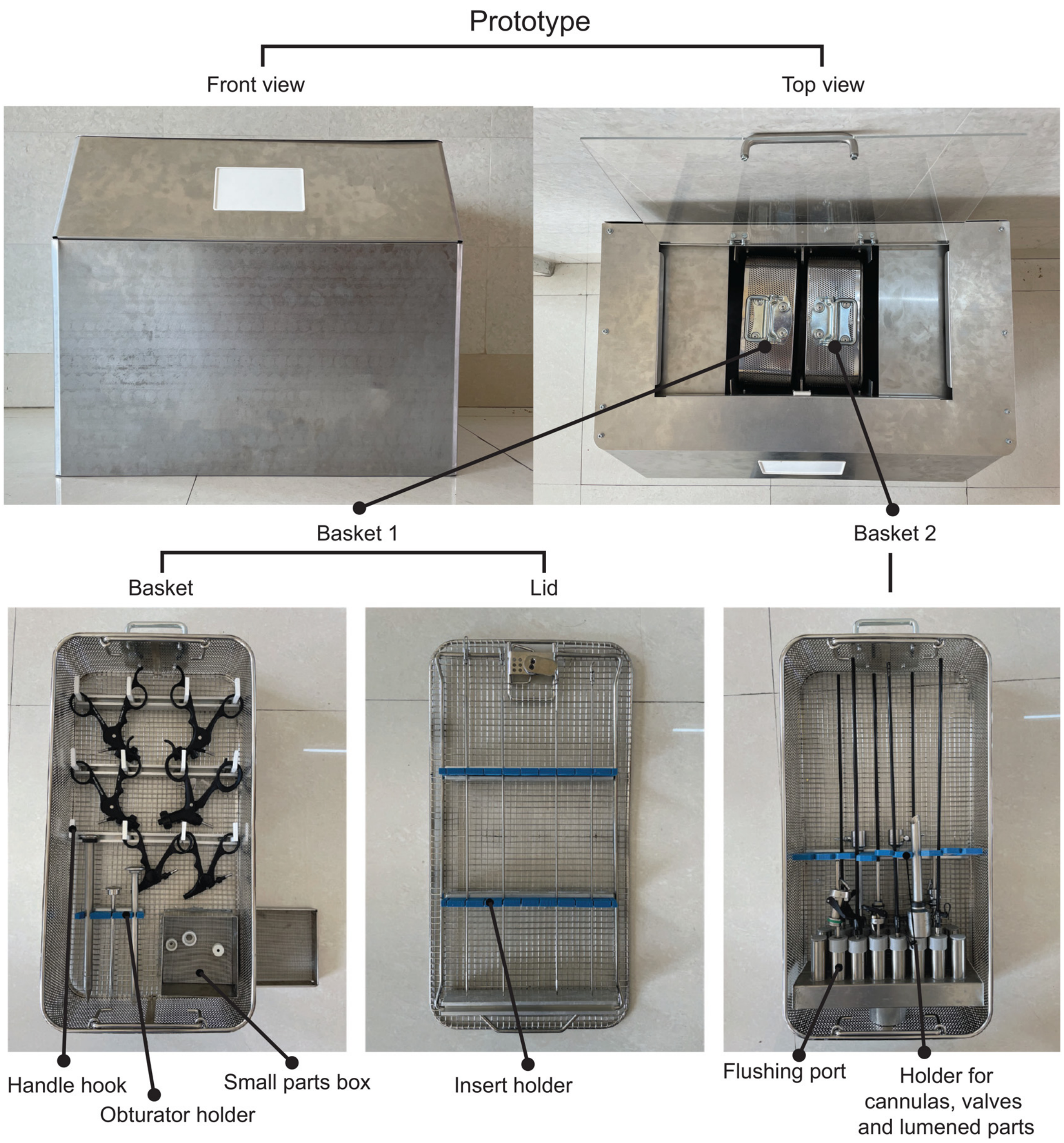

Fig. 6 The prototype used for the usability evaluation (top) with the two loading baskets containing laparoscopic instruments (bottom)

the instruments are washed with water and detergent. One study compared manual and automatic reprocessing of endoscopes in emerging economies, it showed that automated cleaning saves cost, labor time, and improves the lifespan of the endoscopes [35], although the manufacturer instructions were not always followed.

Design Process. A significant portion of the project focused on the design and evaluation of the loading system of the laparoscopic instrument cleaner. This component was chosen due to its prominence in the user interaction with the device. The design of the loading system was initially influenced by systems used in industry, with the assumption that nurses, experienced in handling surgical instruments, would intuitively adapt to these systems. However, the user evaluation revealed that this was not the case. Notably, the root-cause analysis showed that only one of the nurses mentioned cleaning efficacy as an argument for placing an instrument in the basket. This exposed a gap in understanding among nurses regarding the requirements to correctly clean laparoscopic instruments, such as the need to flush hollow parts to remove bioburden. The study illustrated challenges for nurses in this context associated with limited training opportunities and a difficulty in finding reliable information and manuals. Knowledge transfer relied on word of mouth as there was no system for keeping device related manuals and documents. Therefore, the redesign of the loading system primarily focused on providing clear instructions on the device such that it can be operated by all users. However, the effectiveness of these proposed solutions is yet to be fully evaluated.

The Roadmap for the Design of Surgical Equipment for Safe Surgery Worldwide stimulates mapping the context of use of a surgical device and translating this into a set of design requirements [24]. For this project, the context were the factors relating to the reprocessing of laparoscopic instruments: the reprocessing methods were studied, as well as the barriers that workers faced during reprocessing. As Phase 1 showed, there are many barriers that inhibit a reliable sterilization process of laparoscopic instruments; one design would not be able to overcome all of these barriers. It was therefore necessary to define the scope of the key barriers that this design was going to act upon. Phase 0 of the roadmap identifies a need to solve a certain problem. Especially in topics related to healthcare and surgery, this problem is often multifaceted which means that several solution directions can be a result of this phase. We suggest an addition to the roadmap where the scope of the project is defined. This should be a problem analysis, after Phase 0. This

Table 3 Results of the usability study

	Urban ($n = 5$)		Rural ($n = 4$)		Student ($n = 3$)			
Test number	1	2	1	2	1			
Task	Number of errors					Observation	Use error type	Root cause
U1. Unload baskets from cleaner	2	0	0	0	0	Only one basket is unloaded	Cognition	Unclear information from device
A. Loading tasks for basket 1								
A0. Instruments are not assembled before loading	1	1	0	0	0	Assembles instruments	Cognition	Unclear instruction from device
A1. Remove lid from basket	1	0	0	0	0	Unable to open mechanism	Cognition	Unclear information on how to perform action
A2. Load the obturators in the silicone holders	5	2	2	2	3	Puts object in wrong location	Cognition	Unclear information where to place item
A3. Load handles on the hooks	4	0	2	2	3	Puts object in wrong location	Cognition	Unclear information where to place item
A4. Load the inserts in the silicone holders	4	2	3	3	3	Puts object in wrong location	Perception	Correct location is not noticed
A5. Load small parts in the box	1	0	2	1	0	Puts object in wrong location/ Assembles instrument	Cognition	Unclear information where to place item
A6. Attach lid on basket	0	0	0	0	0			
B. Loading tasks for basket 2								
B1. Load black sheaths in the ports	4	4	2	2	2	Puts object in wrong location/Puts object in right location incorrectly	Action/Cognition	The mounting points are too small. Unclear information where to place item
B2. Load trocar cannulas on the rods	4	1	4	2	2	Puts object in wrong location	Cognition	Unclear instruction from device. Unclear information where to place item
B3. Load trocar valves on the rods	5	4	4	4	3	Puts object in wrong location/ Assembles instrument	Cognition	Unclear instruction from device. Unclear information where to place item
L1. Load baskets in cleaner	2	0	1	0	0	Puts object in right location incorrectly	Cognition	Unclear instruction from device
Average time (per group and per test)								
Time (minutes: seconds)	06:34	07:48	07:37	05:54	15:58			

The table shows the required task, the observed result, the use error type (according to IEC62366-1:2020 Annex), and the root cause of the error.

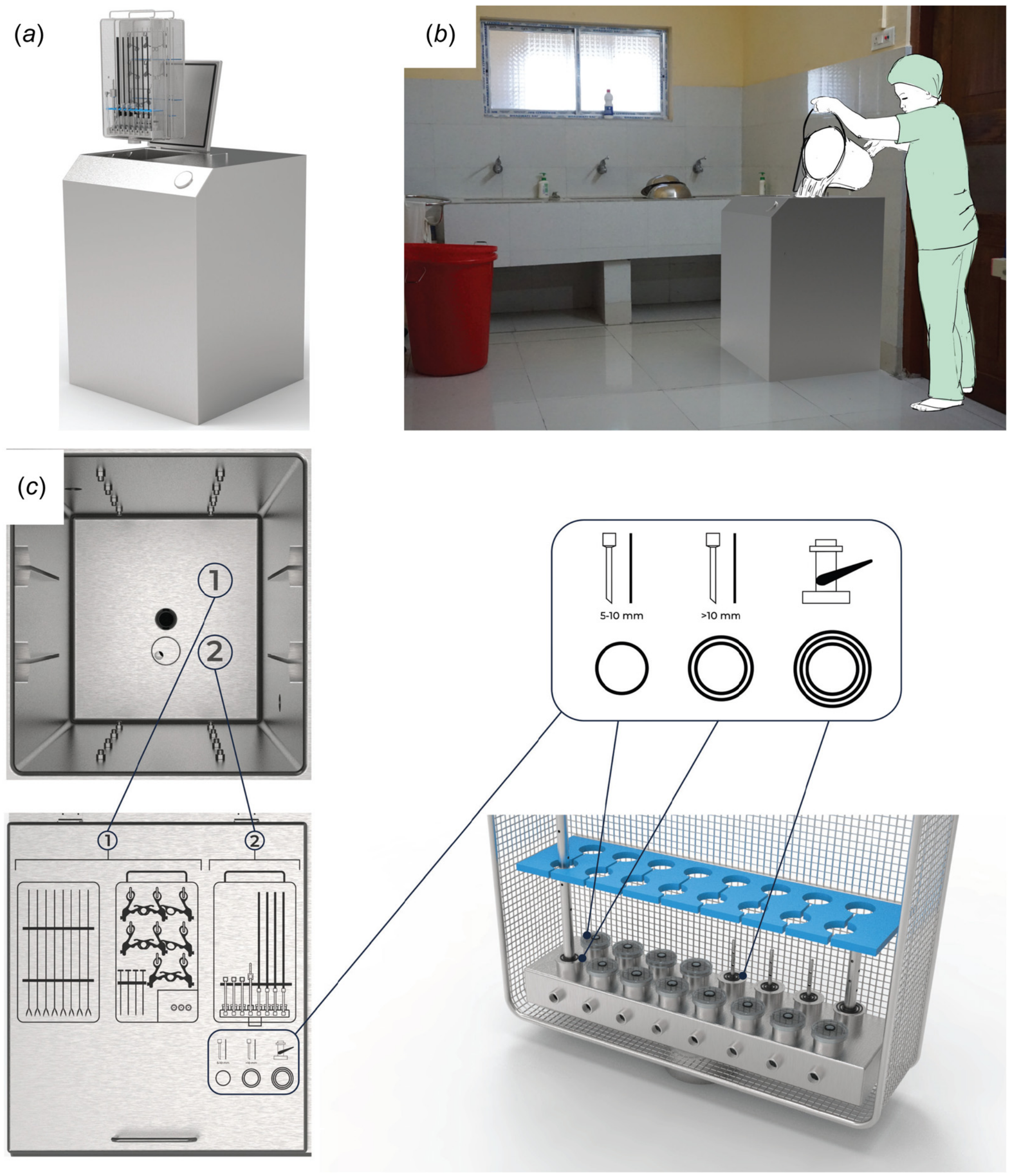

Fig. 7 Rendered image of the redesigned laparoscopic instrument cleaner: (*a*) overview of the cleaner with the instrument baskets, (*b*) render of the cleaner in an operating room environment, and (*c*) redesign with instructions diagrams based on outcomes of the user study

would make the context study phase and the design requirements more specific.

This study made clear that hospitals in LMICs needed tailored solutions to enhance the efficacy and safety of sterile processing in smaller settings. The current focus in improving sterilization in LMIC hospitals has been on the development of training programs, which have demonstrated success [36]. However, no other initiatives were found that aim to improve the reprocessing facilities in low-resource settings.

Limitations and Future Work. The user evaluation was limited by the fidelity of the prototype. The prototype was a nonfunctional device that the nurses could not see in operation. Even though the nurses received information of the method of operation, it could be difficult to imagine for people who had little experience with automated medical cleaners. Future work should include a reevaluation of the loading system to gauge the effectiveness of the proposed solutions. Other solutions in the supply of sterile laparoscopic instruments could be through the use of disposable instruments. Previous economic analyses suggest financial advantages in reusing surgical instruments [37–41]. Furthermore, during our studies, we observed many hospitals reprocessing disposable instruments as a cost-cutting measure. However, novel cost-effective and biodegradable materials could be a solution to these issues.

During the design process for a device such as the laparoscopic instrument cleaner, there are many opportunities to validate design choices. In this approach, the design requirements were translated from the observational studies performed in design Phases 1 and 2. Although additional requirements were suggested by experts, a direct validation of the design requirements by surgeons and nurses in Indian hospitals was not performed.

This study recorded the contextual factors relating to the reprocessing of laparoscopic instruments and the end-users and resulted in a prototype of a laparoscopic instrument cleaner. Further technical development of the device should account for contextual factors such as manufacturability, physical setting, distribution, and how to organize maintenance. These factors will expand the current list of design requirements.

A potential business model is that hospitals will pay for the device per operation cycle and license the machine (medical device as a service). In these schemes, the manufacturer is incentivized to design a robust machine that can easily be maintained.

In later stages of the cleaner's development, training programs have to be created that explain the operation, maintenance, and troubleshooting of the machine. To ensure adoption and comprehension, these instructions should be designed so that prior experience, education, and language do not pose barriers.

Conclusion

In conclusion, this project followed a structured design approach to develop a device for overcoming the challenges in reprocessing laparoscopic instruments in LMIC hospitals. This approach involved comprehensive context mapping, which led to the design of a potential concept. The user evaluation underscored the importance of considering local users' specific needs in designing medical technology, as existing designs may not always align with expectations. This project serves as a stepping stone toward addressing the critical issue of sterile supply in resource-constrained environments, with broader implications for the design of medical devices worldwide.

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Data Availability Statement

The datasets generated and supporting the findings of this article are obtainable from the corresponding author upon reasonable request.

References

[1] Meara, J. G., Leather, A. J. M., Hagander, L., Alkire, B. C., Alonso, N., Ameh, E. A., Bickler, S. W., et al., 2015, "Global Surgery 2030: Evidence and Solutions for Achieving Health, Welfare, and Economic Development," Lancet, **386**(9993), pp. 569–624.

[2] Numanoglu, A., 2017, "Using Telemedicine to Teach Paediatric Surgery in Resource-Limited Countries," Pediatr. Surg. Int., **33**(4), pp. 471–474.

[3] Tansley, G., Bailey, J. G., Gu, Y., Murray, M., Livingston, P., Georges, N., and Hoogerboord, M., 2016, "Efficacy of Surgical Simulation Training in a Low-Income Country," World J. Surg., **40**(11), pp. 2643–2649.

[4] Damas, E., Norcéide, C., Zephyr, Y., Williams, K.-L., Renouf, T., and Dubrowski, A., 2016, "Development of a Sustainable Simulator and Simulation Program for Laparoscopic Skills Training in Haiti," Cureus, **8**(6), p. e632.

[5] Rosenbaum, A. J., and Maine, R. G., 2019, "Improving Access to Laparoscopy in Low-Resource Settings," Ann. Global Health, **85**(1), p. 6.

[6] Gundavda, M. K., and Bhandarwar, A. H., 2012, "Comparative Study of Laparoscopic Versus Open Appendicectomy," Indian J. Med. Sci., **66**(5), pp. 99–115.

[7] Basukala, S., Thapa, N., Bhusal, U., Shrestha, O., Karki, S., Regmi, S. K., Shah, K. B., and Shah, A., 2023, "Comparison of Outcomes of Open and Laparoscopic Appendectomy: A Retrospective Cohort Study," Health Sci. Rep., **6**(8), p. e1483.

[8] Kumar, S., Jalan, A., Patowary, B. N., and Shrestha, S., 2016, "Laparoscopic Appendectomy Versus Open Appendectomy for Acute Appendicitis: A Prospective Comparative Study," Kathmandu Univ. Med. J., **55**, pp. 244–248.

[9] Adisa, A. O., Lawal, O. O., Arowolo, O. A., and Alatise, O. I., 2013, "Local Adaptations Aid Establishment of Laparoscopic Surgery in a Semiurban Nigerian Hospital," Surg. Endosc. Other Interventional Tech., **27**(2), pp. 390–393.

[10] Chao, T. E., Mandigo, M., Opoku-Anane, J., and Maine, R., 2016, "Systematic Review of Laparoscopic Surgery in Low- and Middle-Income Countries: Benefits, Challenges, and Strategies," Surg. Endosc. Other Interventional Tech., **30**(1), pp. 1–10.

[11] O'Hara, N. N., Patel, K. R., Caldwell, A., Shone, S., and Bryce, E. A., 2015, "Sterile Reprocessing of Surgical Instruments in Low- and Middle-Income Countries: A Multicenter Pilot Study," Am. J. Infect. Control, **43**(11), pp. 1197–1200.

[12] Forrester, J. A., Powell, B. L., Forrester, J. D., Fast, C., and Weiser, T. G., 2018, "Surgical Instrument Reprocessing in Resource-Constrained Countries: A Scoping Review of Existing Methods, Policies, and Barriers," Surg. Infect. (Larchmt), **19**(6), pp. 593–602.

[13] Fast, O., Fast, C., Fast, D., Veltjens, S., Salami, Z., and White, M. C., 2017, "Limited Sterile Processing Capabilities for Safe Surgery in Low-Income and Middle-Income Countries: Experience in the Republic of Congo, Madagascar and Benin," BMJ Global Health, **2**(Suppl. 4), p. e000428.

[14] Varela, J. E., Wilson, S. E., and Nguyen, N. T., 2010, "Laparoscopic Surgery Significantly Reduces Surgical-Site Infections Compared With Open Surgery," Surg. Endosc., **24**(2), pp. 270–276.

[15] Mandal, D., Kumar Goswami, D., Kumar Roy, D., and Professor, A., 2017, "The Frequency of Port-Site Infection in Laparoscopic Cholecystectomies—A Retrospective Study," IOSR J. Dent. Med. Sci. (IOSR-JDMS), **16**, pp. 23–29.

[16] Vijayaraghavan, R., Chandrashekhar, R., Sujatha, Y., and Belagavi, C. S., 2006, "Hospital Outbreak of Atypical Mycobacterial Infection of Port Sites After Laparoscopic Surgery," J. Hosp. Infect., **64**(4), pp. 344–347.

[17] Ramesh, H., Prakash, K., Lekha, V., Jacob, G., Venugopal, A., and Venugopal, B., 2003, "Port-Site Tuberculosis After Laparoscopy: Report of Eight Cases," Surg. Endosc. Other Interventional Tech., **17**(6), pp. 930–932.

[18] Weinshel, K., Dramowski, A., Hajdu, Á., Jacob, S., Khanal, B., Zoltán, M., Mougkou, K., Phukan, C., Staneloni, M. I., and Singh, N., 2015, "Gap Analysis of Infection Control Practices in Low- and Middle-Income Countries," Infect. Control Hosp. Epidemiol., **36**(10), pp. 1208–1214.

[19] Webb, M. M., Bridges, P., Aruparayil, N., Chugh, C., Beacon, T., Singh, T., Sawhney, S. S., et al., 2022, "The RAIS Device for Global Surgery: Using a Participatory Design Approach to Navigate the Translational Pathway to Clinical Use," IEEE J. Transl. Eng. Health Med., **10**, pp. 1–12.

[20] Oosting, R. M., Ouweltjes, K., Hoeboer, M. D. B., Hesselink, L., Madete, J. K., Diehl, J. C., Groen, R. S., Wauben, L. S. G. L., and Dankelman, J., 2020, "A Context-Specific Design of an Electrosurgical Unit and Monopolar Handheld to Enhance Global Access to Surgical Care: A Design Approach Based on Contextual Factors," ASME J. Med. Devices, **14**(1), p. 011106.

[21] Aranda-Jan, C. B., Jagtap, S., and Moultrie, J., 2016, "Towards a Framework for Holistic Contextual Design for Low-Resource Settings," Int. J. Des., **10**, pp. 43–63.

[22] Howitt, P., Darzi, A., Yang, G.-Z., Ashrafian, H., Atun, R., Barlow, J., Blakemore, A., et al., 2012, "Technologies for Global Health," Lancet, **380**(9840), pp. 507–535.

[23] Marriott Webb, M., Bridges, P., Aruparayil, N., Mishra, A., Bains, L., Hall, R., Gnanaraj, J., and Culmer, P., 2021, "Designing Devices for Global Surgery: Evaluation of Participatory and Frugal Design Methods," Int. J. Surg.: Global Health, **4**(1), p. e50.

[24] Oosting, R. M., Dankelman, J., Wauben, L. S. G. L., Madete, J., and Groen, R. S., 2019, "Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide," Proceedings of the IEEE Global Humanitarian Technology Conference (GHTC 2018), San Jose, CA, Oct. 18–21, pp. 1–8.

[25] Robertson, D., Gnanaraj, J., Wauben, L., Huijs, J., Samuel, V. M., Dankelman, J., and Horeman-Franse, T., 2021, "Assessment of Laparoscopic Instrument Reprocessing in Rural India: A Mixed Methods Study," Antimicrob. Resist. Infect. Control, **10**(1), p. 109.

[26] World Health Organization, Pan American Health Organization, 2016, *Decontamination and Reprocessing of Medical Devices for Health-Care Facilities*, 1st ed., WHO Document Production Services, Geneva, Switzerland.

[27] ASTM International, 2016, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments," ASTM International, West Conshohocken, PA, Standard No. F1744-96.

[28] Rutala, W. A., and Weber, D. J., and Healthcare Infection Control Practices Advisory Committee (HICPAC), 2019, "Guideline for Disinfection and Sterilization in Healthcare Facilities," Atlanta, GA, accessed Sept. 26, 2024, https://www.cdc.gov/infection-control/media/pdfs/Guideline-Disinfection-H.pdf

[29] Ling, M. L., Ching, P., Widitaputra, A., Stewart, A., Sirijindadirat, N., and Thu, L. T. A., 2018, "APSIC Guidelines for Disinfection and Sterilization of Instruments in Health Care Facilities," Antimicrob. Resist. Infect. Control, **7**(1), p. 25.

[30] Advanced Sterilisation Products, 2016, "CIDEX OPA Ortho-Phthalaldehyde Solution High Level Disinfectant for Semi-Critical Medical Devices Active Instructions for Use," Advanced Sterilisation Products, Irvine, CA, accessed Feb. 21, https://www.asp.com/products/cidex-opa-solution

[31] International Organization for Standardization, 2021, "Washer-Disinfectors—Part 5: Performance Requirements and Test Method Criteria for Demonstrating Cleaning Efficacy," ISO, Geneva, Switzerland, Standard No. ISO 15883-5.

[32] Reeves, T., Mendat, C., and Shaver, E., 2019, "Root Cause Analysis," *Applied Human Factors in Medical Device Design*, Elsevier, Cambridge, MA, pp. 219–236.

[33] International Electrotechnical Commission (IEC), 2016, "Medical Devices—Part 2: Guidance on the Application of Usability Engineering to Medical Devices," International Electrotechnical Commission (IEC), Geneva, Switzerland, Standard No. IEC62366-2:2016.

[34] Alfa, M. J., and Nemes, R., 2004, "Manual Versus Automated Methods for Cleaning Reusable Accessory Devices Used for Minimally Invasive Surgical Procedures," J. Hosp. Infect., **58**(1), pp. 50–58.
[35] Funk, S. E., and Reaven, N. L., 2014, "High-Level Endoscope Disinfection Processes in Emerging Economies: Financial Impact of Manual Process Versus Automated Endoscope Reprocessing," J. Hosp. Infect., **86**(4), pp. 250–254.
[36] Fast, O., Dosani, A., Uzoka, F. M., Cuncannon, A., and Cheav, S., 2020, "Improving Sterile Processing Practices in Cambodian Healthcare Facilities," Infect. Prev. Pract., **2**(4), p. 100101.
[37] Adler, S., Scherrer, M., Rückauer, K. D., and Daschner, F. D., 2005, "Comparison of Economic and Environmental Impacts Between Disposable and Reusable Instruments Used for Laparoscopic Cholecystectomy," Surg. Endosc. Other Interventional Tech., **19**(2), pp. 268–272.
[38] Chan, A. C. W., Ip, M., Koehler, A., Crisp, B., Tam, J. S., and Chung, S. C. S., 2000, "Is It Safe to Reuse Disposable Laparoscopic Trocars?: An In Vitro Testing," Surg. Endosc., **14**(11), pp. 1042–1044.
[39] Colak, T., Ersoz, G., Akca, T., Kanik, A., and Aydin, S., 2004, "Efficacy and Safety of Reuse of Disposable Laparoscopic Instruments in Laparoscopic Cholecystectomy: A Prospective Randomized Study," Surg. Endosc. Other Interventional Tech., **18**(5), pp. 727–731.
[40] Siu, J., Hill, A. G., and MacCormick, A. D., 2017, "Systematic Review of Reusable Versus Disposable Laparoscopic Instruments: Costs and Safety," ANZ J. Surg., **87**(1–2), pp. 28–33.
[41] De Grandi, P., Chardonnens, E., Gerber, S., Davila, F., Tsin, D. A., Dominguez, G., Davila, U., et al., 2015, "Systematic Review of Reusable Versus Disposable Laparoscopic Instruments: Costs and Safety," Surg. Laparosc. Endosc. Percutaneous Tech., **27**, pp. 28–33.